

### REMARKS

In response to the Office Action mailed October 6, 2005, Applicants cancelled claims 1-73, 75, 85, 93, 105 and 119 and amended claims 74, 78-80, 82-84, 88, 89, 91, 92, 96-99, 101-104, 108-112, 114-118, 122-125 and 127-129. Applicants also added new claims 130-139. Claims 74, 76-84, 86-92, 94-104, 106-118 and 120-139 are presented for examination.

#### **Rejection of claims 74-129 under 35 U.S.C. §112, first paragraph**

The Examiner rejected claims 74-129 under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement.<sup>1</sup>

With respect to the Examiner's concern regarding the polymeric materials disclosed in the paragraph bridging pages 12 and 13 of the application, Applicants amended the claims to cover polyesters. The application includes a relatively lengthy discussion regarding exemplary methods of making articles covered by pending claims, as well as numerous specific examples where articles covered by pending claims were made. (Id. at pages 17-28.)

Regarding the term "load at break ratio", while the definition of this term is not explicitly disclosed in the application, Applicants believe that, after reading the application, one skilled in the art would understand what is meant by this term. In addition to disclosing the "load at break ratio", Applicants disclose two other "ratio" parameters -- the "tensile strength ratio" and the "hoop stress ratio". (See, e.g., id. at page 24.) For the tensile strength ratio, Applicants disclose (see, e.g., id.):

As used herein the tensile strength ratio of a catheter component material is determined by dividing the tensile strength of the material as a tube-shaped catheter component (according to one or more of the procedures described above) by the tensile strength of the material before being longitudinally or radially stretch-blown (e.g., as an extruded tube).

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<sup>1</sup> Applicants cancelled claims 75, 85, 93, 99, 105 and 119, so the rejection of these claims should be withdrawn

And, for the hoop stress ratio, Applicants disclose (see, e.g., id.):

As used herein, the hoop stress ratio of a catheter component material is determined by dividing the hoop stress of the material as a tube-shaped catheter component (according to the procedure described above) by the hoop stress of the material before being longitudinally or radially stretch-blown (e.g., as an extruded tube).

Thus, it is apparent that one skilled in the art would understand that the load at break ratio of a catheter component material is determined by dividing the load at break of the material as a tube-shaped catheter component (according to one or more of the procedures described in the application) by the load at break of the material before being longitudinally or radially stretch-blown (e.g., as an extruded tube).

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

**Rejection of claims 74-78 and 80-82 under 35 U.S.C. §102(b)**

The Examiner rejected claims 74-78 and 80-82 under 35 U.S.C. §102(b) as being anticipated by Pinchuk.<sup>2</sup>

Claims 74, 76-78 and 80-82 cover articles with a tube-shaped region that: 1.) include a polyester having a tensile strength of at least about 21,000 psi; and 2.) are adapted to be bonded to a hypotube.

Pinchuk does not disclose such articles. Rather, Pinchuk discloses balloon catheters in which the balloon-portion is reported to:

have a calculated tensile strength of between about 15,000 and about 35,000 psi and above, preferably between about 20,000 and about 32,000 psi. (Pinchuk col. 11, lines 13-21.)

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<sup>2</sup> Applicants cancelled claim 75, so the rejection of this claim should be withdrawn

It is unclear to Applicants what Pinchuk means by a "calculated" tensile strength, or how this might compare to the tensile strength defined in Applicants' specification. As a result, Applicants do not concede that Pinchuk's "calculated" tensile strengths correspond to the tensile strength required by claims 74, 76-78 and 80-82. Further, Pinchuk is referring to the balloon portion of his device when he discusses the noted "calculated" tensile strengths. As a result, even if Pinchuk's "calculated" tensile strength corresponded to the tensile strength required by claims 74, 76-78 and 80-82, Pinchuk is referring to a region of his device that is not adapted to be bonded to a hypotube. Applicants therefore request reconsideration and withdrawal of the rejection of claims 74, 76-78 and 80-82 under 35 U.S.C. §102(b).

**Rejection of Claims 79 and 83 under 35 U.S.C. §103(a)**

The Examiner rejected claims 79 and 83 under 35 U.S.C. §103(a) as being unpatentable over Pinchuk in view of Sahatjian.

Claims 79 and 83 cover articles with a tube-shaped region that: 1.) include a polyester having a tensile strength of at least about 21,000 psi; and 2.) are adapted to be bonded to a hypotube.

As discussed above, Pinchuk does not disclose such components. Nor is there any suggestion to modify Pinchuk to provide such components. Even if there were a suggestion to modify Pinchuk by combination with Sahatjian in the manner indicated by the Examiner, the result would not be the components covered by claims 79 and 83, at least because, like Pinchuk, Sahatjian does not disclose or suggest articles with a tube-shaped region that: 1.) include a polyester having a tensile strength of at least about 21,000 psi; and 2.) are adapted to be bonded to a hypotube.

Applicants therefore request reconsideration and withdrawal of the rejection of claims 79 and 83 under 35 U.S.C. §103(a).

**Rejection of claims 84-86, 88, 89 and 91 under 35 U.S.C. §102(b)**

The Examiner rejected claims 84-86, 88, 89 and 91 under 35 U.S.C. §102(b) as being anticipated by Sahatjian.<sup>3</sup>

Claims 84-86, 88, 89 and 91 cover articles with a tube-shaped region that: 1.) include a polyester having a hoop stress of at least about 3300 psi; and 2.) are adapted to be bonded to a hypotube.

Sahatjian does not disclose such articles. Instead, Sahatjian discloses balloons that have a “hoop stress at failure” of greater than about 36,000 psi. (Sahatjian col. 1, lines 50-51.) It is unclear to Applicants whether Sahatjian’s “hoop stress at failure” is the same as the “hoop stress” required by claims 84-86, 88, 89 and 91. In addition, Sahatjian is referring to a balloon when he discloses the noted “hoop stress at failure” value. Accordingly, even if Sahatjian’s “hoop stress at failure” corresponded to the hoop stress required by claims 84-86, 88, 89 and 91, Sahatjian is referring to a region of his device that is not adapted to be bonded to a hypotube. Applicants therefore request reconsideration and withdrawal of the rejection of claims 84-86, 88, 89 and 91 under 35 U.S.C. §102(b).

**Rejection of claims 87 and 90 under 35 U.S.C. §103(a)**

The Examiner rejected claims 87 and 90 under 35 U.S.C. §103(a) as being unpatentable over Sahatjian in view of Pinchuk.

Claims 87 and 90 cover articles with a tube-shaped region that: 1.) include a polyester having a hoop stress of at least about 3300 psi; and 2.) are adapted to be bonded to a hypotube.

As discussed above, Sahatjian does not disclose such components. Nor is there any suggestion to modify Sahatjian to provide such components. Even if there were a suggestion to modify Sahatjian by combination with Pinchuk in the manner indicated by the Examiner, the result would not be the components covered by claims 87 and 90, at least because, like Sahatjian, Pinchuk does not disclose or suggest articles with a tube-shaped region that: 1.) include a

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<sup>3</sup> Applicants cancelled claim 85, so the rejection of this claim should be withdrawn

polyester having a hoop stress of at least about 3300 psi; and 2.) are adapted to be bonded to a hypotube.

Applicants therefore request reconsideration and withdrawal of the rejection of claims 87 and 90 under 35 U.S.C. §103(a).

**Rejection of claims 104-109 and 112-115 under 35 U.S.C. §102(b)**

The Examiner rejected claims 104-109 and 112-115 under 35 U.S.C. §102(b) as being anticipated by Pinchuk.<sup>4</sup>

Claims 104, 106-109 and 112-115 cover articles with a tube-shaped region that: 1.) include a polyester having a hoop stress ratio of at least about 1.25; and 2.) are adapted to be bonded to a hypotube.

Pinchuk does not disclose such articles. Rather, Pinchuk discloses:

The relationship between balloon tailorability and hoop expansion ratio is illustrated in FIG. 7. Three non-sterilized nylon balloons having different hoop expansion ratios were tested at 37.degree. C., the expansion being to burst. A relatively high hoop expansion ratio of 4.9 (curve N) gave a balloon distention (safely short of burst) of about 7 percent. A 3.7 hoop expansion ratio (curve O) gave a balloon distention of about 23 percent, while a 3.3 hoop expansion ratio (curve P) gave a balloon distention of about 36 percent. (Pinchuk col. 13, lines 13-21.)

It is unclear to Applicants what Pinchuk means by a "hoop expansion ratio", or how this might compare to the hoop stress ratio defined in Applicants' specification. As a result, Applicants do not concede that Pinchuk's "hoop expansion ratio" corresponds to the hoop stress ratio required by claims 104, 106-109 and 112-115. Further, Pinchuk is referring to the balloon portion of his device when he discusses the noted "hoop expansion ratio". As a result, even if Pinchuk's "hoop expansion ratio" corresponded to the hoop stress ratio required by claims 104, 106-109 and 112-115, Pinchuk is referring to a region of his device that is not adapted to be bonded to a hypotube.

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<sup>4</sup> Applicants cancelled claim 105, so the rejection of this claim should be withdrawn

Applicants therefore request reconsideration and withdrawal of the rejection of claims 104, 106-109 and 112-115 under 35 U.S.C. §102(b).

**Rejection of Claims 110 and 116 under 35 U.S.C. §103(a)**

The Examiner rejected claims 110 and 116 under 35 U.S.C. §103(a) as being unpatentable over Pinchuk in view of Sahatjian.

Claims 110 and 116 cover articles with a tube-shaped region that: 1.) include a polyester having a hoop stress ratio of at least about 1.25; and 2.) are adapted to be bonded to a hypotube.

As discussed above, Pinchuk does not disclose such components. Nor is there any suggestion to modify Pinchuk to provide such components. Even if there were a suggestion to modify Pinchuk by combination with Sahatjian in the manner indicated by the Examiner, the result would not be the components covered by claims 110 and 116, at least because, like Pinchuk, Sahatjian does not disclose or suggest articles with a tube-shaped region that: 1.) include a polyester having a hoop stress ratio of at least about 1.25; and 2.) are adapted to be bonded to a hypotube.

Applicants therefore request reconsideration and withdrawal of the rejection of claims 110 and 116 under 35 U.S.C. §103(a).

**Rejection of claims 118-123 and 125-128 under 35 U.S.C. §102(b)**

The Examiner rejected claims 118-123 and 125-128 under 35 U.S.C. §102(b) as being anticipated by Pinchuk.<sup>5</sup>

Claims 118, 120-123 and 125-128 cover articles with a tube-shaped region that: 1.) include a polyester having a post buckle fracture tensile strength of at least about 6500 psi; and 2.) are adapted to be bonded to a hypotube.

Pinchuk does not disclose such articles. Indeed, Pinchuk is silent regarding the post buckle fracture tensile strength of this articles. In making the rejection, the Examiner appears to have relied on the portion of Pinchuk that discloses:

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<sup>5</sup> Applicants cancelled claim 119, so the rejection of this claim should be withdrawn

have a calculated tensile strength of between about 15,000 and about 35,000 psi and above, preferably between about 20,000 and about 32,000 psi. (Pinchuk col. 11, lines 13-21.)

It is unclear to Applicants what Pinchuk means by a "calculated" tensile strength, or how this might compare to the post buckle fracture tensile strength defined in Applicants' specification. As a result, Applicants do not concede that Pinchuk's "calculated" tensile strengths correspond to the post buckle fracture tensile strength required by claims 118, 120-123 and 125-128. Further, Pinchuk is referring to the balloon portion of his device when he discusses the noted "calculated" tensile strengths. As a result, even if Pinchuk's "calculated" tensile strength corresponded to the post buckle fracture tensile strength required by claims 118, 120-123 and 125-128, Pinchuk is referring to a region of his device that is not adapted to be bonded to a hypotube. Applicants therefore request reconsideration and withdrawal of the rejection of claims 118, 120-123 and 125-128 under 35 U.S.C. §102(b).

**Rejection of Claims 124 and 129 under 35 U.S.C. §103(a)**

The Examiner rejected claims 124 and 129 under 35 U.S.C. §103(a) as being unpatentable over Pinchuk in view of Sahatjian.

Claims 124 and 129 cover articles with a tube-shaped region that: 1.) include a polyester having a post buckle fracture tensile strength of at least about 6500 psi; and 2.) are adapted to be bonded to a hypotube.

As discussed above, Pinchuk does not disclose such components. Nor is there any suggestion to modify Pinchuk to provide such components. Even if there were a suggestion to modify Pinchuk by combination with Sahatjian in the manner indicated by the Examiner, the result would not be the components covered by claims 124 and 129, at least because, like Pinchuk, Sahatjian does not disclose or suggest articles with a tube-shaped region that: 1.) include a polyester having a post buckle fracture tensile strength of at least about 6500 psi; and 2.) are adapted to be bonded to a hypotube.

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Serial No. : 10/669,059  
Filed : September 23, 2003  
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Attorney's Docket No.: 10527-477001 / 01-D1160

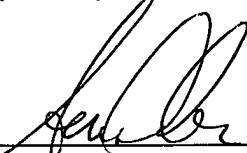
Applicants therefore request reconsideration and withdrawal of the rejection of claims 124 and 129 under 35 U.S.C. §103(a).

Applicants believe the application is in condition for allowance, which action is requested.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 12/23/05

  
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